UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ABBVIE INC. and ABBVIE BIOTECHNOLOGY LIMITED,

Plaintiffs,

-against-

THE KENNEDY TRUST FOR RHEUMATOLOGY RESEARCH,

Defendant.

13 Civ. 1358 (PAC)

OPINION & ORDER

HONORABLE PAUL A. CROTTY, United States District Judge:

This is a patent validity dispute regarding a method for treating rheumatoid arthritis ("RA"). The validity of a similar patent was the subject of a related case between the same parties in this Court (the "Prior Action"). Following a four-day bench trial, the Court found that certain claims of U.S. Patent No. 7,846,442 ("the '442 Patent") were invalid for obviousness-type double patenting ("ODP") over certain claims of U.S. Patent No. 6,270,766 ("the '766 Patent"). *Abbvie Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Trust*, 956 F. Supp. 2d 429, 493 (S.D.N.Y. 2013) (the "Prior Decision"). Plaintiffs now move for summary judgment declaring claims of a similar patent, U.S. Patent No. 8,383,120 ("the '120 Patent"), invalid on the grounds of collateral estoppel. For the reasons set forth below, the motion is granted.

BACKGROUND

The RA treatment at issue involves co-administering anti– tumor necrosis factor alpha ("TNFα") antibodies with the well-known drug methotrexate. Defendant The Kennedy Trust for Rheumatology Research ("Kennedy") holds a patent for certain methods of this treatment—the

'766 Patent—which expired on October 8, 2012. Plaintiffs Abbvie Inc. and Abbvie Biotechnology Limited (collectively, "Abbvie") have paid more than $100 million in royalties to license the use of the '766 Patent in Abbvie's prescription drug marketed as Humira®. *See* Prior Decision, 956 F. Supp. 2d 429, ¶¶ 266–69. The '442 Patent at issue in the Prior Action had a later expiration date due to its later effective filing date,[1] and Kennedy demanded continued royalty payments from Abbvie on the basis of the '442 Patent. *See id.* ¶ 270.

In the Prior Decision, the Court found that Abbvie had proven by clear and convincing evidence that the disputed claims in the '442 Patent[2] were obvious variants of claims in the '766 Patent and therefore invalid under the ODP doctrine. *See* 956 F. Supp. 2d at 493. The Court presumes familiarity with its Prior Decision, including its findings regarding the prior art, the person of ordinary skill in the art ("POSA"), and its construction of the claims of the '766 and '442 Patents. *See generally id.*

After trial, but before the Court issued its decision, Kennedy obtained a third patent for a similar RA treatment—the '120 Patent—which contains the claims in dispute here.[3] In this motion, Abbvie contends that the '120 Patent is likewise invalid as a matter of collateral estoppel because the differences between the '442 and '120 Patents do not vary the issues bearing on the ODP analysis.

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[1] The '442 Patent would have expired on "August 21, 2018, which is twenty years from the effective filing date of August 1, 1996, plus an additional 750 days the PTO added under 35 U.S.C. § 154(b)." Prior Decision, 956 F. Supp. 2d 429, ¶ 251.

[2] In the Prior Action, the parties stipulated that only certain claims of the '442 Patent were in dispute: claims 1–7, 13–14, and 17–20. (*See* Shehigian Decl. Ex. 10.) Unless otherwise noted, references to the '442 Patent are only to those claims.

[3] As in the Prior Action, the parties have stipulated that only certain claims of the '120 Patent are in dispute: claims 1–2, 6–8, 12–14, 18, and 19 ("insofar as it depends from" any of the other disputed claims). (*See* Dkt. 26.) Unless otherwise noted, references to the '120 Patent are only to those claims.

There is no dispute that (1) the '442 Patent and the '120 Patent share the same effective filing date (August 1, 1996); (2) the specifications of the two patents are identical (aside from the claim language); (3) Kennedy offers no new studies or data to support the nonobviousness of the '120 Patent; and (4) the '120 Patent claims a narrowed species of the broader genus claimed in the '442 Patent. Kennedy argues that although the newly worded claims may be logically "encompassed by" the previously invalidated claims, they nonetheless raise new questions about obviousness that are not precluded by collateral estoppel.

DISCUSSION

I. Legal Standards

A. Summary Judgment

"Summary judgment is appropriate when, construing the evidence in the light most favorable to the non-moving party, 'there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.'" *Rojas v. Roman Catholic Diocese of Rochester*, 660 F.3d 98, 104 (2d Cir. 2011) (quoting Fed. R. Civ. P. 56(a)). A fact is material only if it "might affect the outcome of the suit under the governing law," and a factual dispute is genuine only if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). The moving party bears the initial burden of producing evidence on each material element of its claim or defense demonstrating that it is entitled to relief as a matter of law. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). The Court resolves all ambiguities and draws all factual inferences in favor of the nonmovant, but "only if there is a 'genuine' dispute as to those facts." *Scott v. Harris*, 550 U.S. 372, 380 (2007).

B. Obviousness-Type Double Patenting ("ODP")

The Prior Decision set forth the legal standards for the ODP doctrine, which remain applicable here:

> Under 35 U.S.C. § 101, an inventor may obtain "a patent," but only one patent for a single invention. The doctrine of non-statutory, or "obviousness-type," double patenting prevents the extension of the term of a patent via the patenting of an obvious variation of the original patent.
>
> Obviousness-type double patenting is a judicially-created doctrine designed to prevent claims in separate applications or patents that do not recite the same invention, but nonetheless claim inventions so alike that granting both exclusive rights would effectively extend the life of patent protection. . . .
>
> The doctrine of obviousness-type double patenting prohibits claims in a second patent that are "not patentably distinct from" claims in an earlier patent. Two claims are not "patentably distinct" if the later claim would have been obvious to a person of ordinary skill in the art based on the earlier claim, in light of the prior art. . . .
>
> In determining whether the claims at issue are patentably distinct, the Court does not consider the differences in the claims in isolation, but must consider the claims "as a whole."

956 F. Supp. 2d at 473–74 (citations and quotation marks omitted).

C. Collateral Estoppel

"Collateral estoppel, or issue preclusion, prevents parties or their privies from relitigating in a subsequent action an issue of fact or law that was fully and fairly litigated in a prior proceeding." *Marvel Characters, Inc. v. Simon*, 310 F.3d 280, 288 (2d Cir. 2002). To succeed on a motion for summary judgment based on collateral estoppel, the movant must demonstrate that "(1) the identical issue was raised in a previous proceeding; (2) the issue was actually litigated and decided in the previous proceeding; (3) the party had a full and fair opportunity to litigate the issue; and (4) the resolution of the issue was necessary to support a valid and final judgment on the merits." *Id.* at 288–89 (internal quotations omitted). While Second Circuit

precedent governs this Court's general application of collateral estoppel, Federal Circuit precedent governs "those aspects of such a determination that involve substantive issues of patent law." *Ohio Willow Wood Co. v. Alps S., LLC*, 735 F.3d 1333, 1342 (Fed. Cir. 2013).

In patent validity cases, the "first consideration" in the collateral estoppel analysis is "whether the issue of invalidity common to each action is substantially identical." *Bourns, Inc. v. United States*, 537 F.2d 486, 491 (Ct. Cl. 1976) (quotations omitted).[4] "To assess the identity of th[e] issues, it is convenient to compare the adjudicated and unadjudicated claims." *Id.* at 493. A prior obviousness determination is preclusive "[w]here the differences revealed by a comparison of the claims do not vary the relevant issues bearing on obviousness." *Id.* The relevant issues are "the art pertinent to the nonlitigated claims," "the scope and content of that art," "the differences between the prior art and the nonlitigated claims," and "the level of ordinary skill in that art." *Westwood Chem., Inc. v. U. S.*, 525 F.2d 1367, 1375 (Ct. Cl. 1975).

Importantly, "[i]t is the issues litigated, not the specific claims around which the issues were framed, that is determinative." *Id.* at 1367. "[M]erely because the invention, the patentee's contribution to the art, is presented in varying language or varying combinations of elements does not necessarily mean that the issues bearing on the nonobviousness of that concept or contribution vary from one claim to the next." *Bourns*, 537 F.2d at 492. Accordingly, "each of several differently worded claims may present identical issues." *Id.*

The analysis does not turn, however, solely on a comparison of (a) the prior art with (b) the differences between a previously adjudicated claim and the one at issue. Doing so would

[4] The Federal Circuit has adopted as precedent the decisions of the Court of Claims. *S. Corp. v. United States*, 690 F.2d 1368, 1370 (Fed. Cir. 1982) (en banc). In particular, the Federal Circuit has cited with approval the Court of Claims' "pragmatic approach" for applying collateral estoppel in patent cases. *E.g., Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1136 (Fed. Cir. 1985).

erroneously treat the adjudicated claims as prior art. *Bourns*, 537 F.2d at 492–93 ("A domino approach in which each successively narrower claim is compared with the one before it, not with the prior art, is inappropriate since it improperly gives prior-art effect to the subject matter of an invalid claim."). Rather, "it is still necessary to assess the importance of the difference to the combination as a whole since it is from that standpoint that the obviousness determination must be made." *Westwood*, 525 F.2d at 1375. Thus, the question is whether "the additional elements recited in the unadjudicated claims . . . distinguish the claimed combination as a whole from the prior art." *Bourns*, 537 F.2d at 493. "[I]n the end, application of [collateral] estoppel 'will necessarily rest on the trial courts' sense of justice and equity.'" *Id.* at 497 (quoting *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 334 (1971)).

II. Collateral Estoppel Analysis

In the Prior Decision, the Court determined that the'442 Patent was not made patentably distinct from the '766 Patent by narrowing the scope of its claims regarding patient population, methods of treatment, antibody types, dosing frequency, mechanism of action, and efficacy. *See* 956 F. Supp. 2d 429, ¶¶ 347–410. Here again with the '120 Patent, Kennedy has narrowed the scope of its claims in these categories but has done so with greater specificity. Since the '442 and '120 Patents share the same effective filing date, the scope of the prior art is identical, and there is no need to revisit the Court's determination regarding the POSA.

Although a patent may issue for a narrower subset of a broader prior claim (*i.e.*, "a species of a genus"), the narrowed claim must not be an obvious variant of the prior claim. *See, e.g., Eli Lilly & Co. v. Barr Labs., Inc.*, 222 F.3d 973, 987 (Fed. Cir. 2000) ("With the [prior] patent now expired, [the patentee] cannot hide behind its once-advantageous broad coverage [of a patent on a genus] . . . and argue that [practicing the species] would not have been obvious.");

Prior Decision, 956 F. Supp. 2d at 476 (invalidating patent of a species of a genus for obviousness-type double patenting); *cf. In re Gleave*, 560 F.3d 1331, 1338 (Fed. Cir. 2009) (genus anticipates a species when "the genus is so limited that a person of ordinary skill in the art can 'at once envisage each member of this limited class.'"). Therefore, the Court must determine whether the further-refined claim language varies the issues bearing on ODP that were adjudicated in the Prior Decision.

The language of the '120 Patent varies from the '442 Patent in all of the respects listed above (*i.e.*, patient population, methods of treatment, antibody types, etc.), but Kennedy defends the '120 Patent's validity on three grounds in particular. *First*, the '120 Patent defines the "disease activity element" in a manner that is "substantially more specific and fundamentally differs from the Court's construction of 'active disease' in the Prior Litigation." (Kennedy Br. at 12.) *Second*, the '120 Patent "require[s] a specific level of therapeutic benefit[,] . . . . whereas the litigated '442 claims require reduction of the signs and symptoms of RA." (*Id.*) *Third*, "the '120 claims explicitly recite the biological mechanism by which the claimed antibody must act, whereas the '442 claims were not so explicit." (*Id.* at 12–13.) The following table sets forth the relevant claim language with respect to these three issues for each of the '766, '442, and '120 Patents:

Issue	'766 Patent	'442 Patent	'120 Patent
Level of Disease in Patient Population	**Claim 8**: "A method of treating rheumatoid arthritis in an individual in need thereof . . . ."	**Claim 1:** "A method of treating an individual suffering from rheumatoid arthritis whose active disease is incompletely controlled despite already receiving methotrexate . . . ."	**Claim 1**: "A method of treating an individual suffering from rheumatoid arthritis who, despite prior treatment with methotrexate, still has active disease, defined as the presence of six or more swollen joints plus at least three of the following four secondary criteria: duration of morning stiffness ≥45 minutes; ≥6 tender or painful joints; erythrocyte sedimentation rate (ESR) ≥28 mm/hour; and C-reactive protein (CRP) ≥20 mg/l . . . ."
Efficacy	**Claim 8:** ". . . in therapeutically effective amounts."	**Claim 1:** ". . . wherein such administration reduces or eliminates signs and symptoms associated with rheumatoid arthritis."	**Claim 1:** ". . . wherein the treatment reduces the individual's signs and symptoms by greater than fifty percent (50%) according to the Paulus criteria for a significant duration of time." **Claim 19:** "The method of any of claims 1-18, wherein the method further results in the individual's rheumatoid arthritis going into remission or near remission."
Mechanism of Action	**Claim 8**: ". . . an anti-tumor necrosis factor alpha antibody or an antigen-binding fragment thereof . . . ."	**Claim 1**: ". . . wherein the anti-human tumor necrosis factor-α antibody or fragment thereof (a) binds to an epitope on human tumor necrosis factor-α, (b) inhibits binding of human tumor necrosis factor-α to human tumor necrosis factor-α cell surface receptors . . . ." **Claim 19**: ". . . wherein the anti-human tumor necrosis factor-α antibody binds specifically to human tumor necrosis factor-α . . . ."	**Claim 1**: ". . . which antibody (a) binds specifically to human tumor necrosis factor-α and (b) inhibits binding of human tumor necrosis factor-α to both p55 and p75 cell surface receptors . . . ."

A. Level of Disease in Patient Population

In the Prior Action, the Court found that "a person of ordinary skill in the art would not consider there to be a substantial difference" between (1) "an individual in need of" treatment for

RA ('766 Patent) and (2) "an individual suffering from rheumatoid arthritis whose active disease is incompletely controlled despite already receiving methotrexate" ('442 Patent). *See* Prior Decision, 956 F. Supp. 2d 429, ¶ 354. In reaching this conclusion, the Court construed "patients with 'active disease'" to mean "patients with continuing signs and symptoms of rheumatoid arthritis despite their ongoing methotrexate treatment." *Id.* ¶ 345. The Court held that "a person of ordinary skill in the art would not be limited to the definition of 'active disease'" urged by Kennedy, which was "the presence of six or more swollen joints plus at least three of four secondary criteria." *Id.* ¶¶ 342–44. Although this definition had been used in clinical trials, the Court determined that a POSA would not be limited to this particular definition. *Id.*

As Abbvie correctly observes, the Prior Decision rejected Kennedy's contention that it would be nonobvious to treat a "sicker subset of patients." (Reply at 3.) Although the Court held that the definition of "active disease" was not "limited to" the one Kennedy now spells out in its claims, Kennedy does not refer to any evidence to raise a genuine dispute that such a circumscribed definition yields a patentably distinct invention. Instead, Kennedy merely refers to evidence that "the treatment regimen for a patient would depend considerably on the signs and symptoms of the patient being treated, and that a POSA would have different treatment plans and different expectations of success depending on the signs and symptoms present." (Opp'n at 15.) Of course, every patient is different, but this does not suggest that treating patients with this particular level of disease requires a different ODP analysis than treating patients whose RA is "incompletely controlled."

B. Efficacy

In the Prior Action, the Court found that narrowing the '766 Patent's claim for a treatment in a "therapeutically effective amount" to the '442 Patent's claim for a treatment that

"reduces or eliminates signs or symptoms associated with rheumatoid arthritis" did not render the latter patentably distinct. *See* Prior Decision, 956 F. Supp. 2d 429, ¶ 366. The Court observed that the former "clearly encompasses" the latter. *Id.*

Here again, Kennedy has narrowed the language regarding efficacy, this time in two separate claims. Claim 1 of the '120 Patent recites a treatment that "reduces the individual's signs and symptoms by greater than fifty percent (50%) according to the Paulus criteria for a significant duration of time." Claim 19 recites a treatment that "results in the individual's rheumatoid arthritis going into remission or near remission." These claims rely on the same data considered in the Prior Action. In support of these claims' nonobviousness, Kennedy cites Dr. Michael Weinblatt's deposition testimony that, as of August 1, 1995, achieving remission was "generally not doable with most of the therapies we had" and is "generally not doable now." (Maldonado Decl. Ex. 14 at 69.)

The claims of increased efficacy, however, do not vary the issues bearing on obviousness for two reasons. First, the Court already determined—on the basis of the same clinical data presented here—that the methods claimed in the '442 Patent did not yield "unexpected results" when compared to those of the '766 Patent. *See* Prior Decision, 956 F. Supp. 2d 429, ¶¶ 370–74. Indeed, the Court heard testimony regarding purportedly surprising results as measured by the Paulus criteria at issue here. (Shehigian Decl. Ex. 7 at 691–92.)

Second, the Prior Decision's observation that the '442 Patent's efficacy claims were "encompassed by" those of the '766 Patent are equally applicable to the '120 Patent. The '442 Patent claimed a treatment that "reduces or eliminates signs or symptoms" of RA, and the '120 Patent merely measures the reduction in terms of the Paulus criteria and uses the word

"remission" in lieu of "eliminates." Even if there were a possible semantic difference,[5] there is not a substantial legal one for purposes of the ODP analysis. "[M]erely discovering and claiming a new benefit of an old process cannot render the process again patentable." *King Pharm., Inc. v. Eon Labs, Inc.*, 616 F.3d 1267, 1275 (Fed. Cir. 2010). That is true even where there are "[n]ewly discovered results of known processes directed to the same purpose . . . because such results are inherent." *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1376 (Fed. Cir. 2001). Accordingly, the '120 Patent raises no new ODP issues with respect to the treatment's efficacy.

C. Mechanism of Action

The Prior Decision found that reciting the anti–TNFα antibodies' mechanism of action did not render the '442 claims patentably distinct from the '766 claims. *See* 956 F. Supp. 2d 429, ¶¶ 359–61. While the '766 Patent does not recite a mechanism of action, the '442 Patent did so as follows: the anti–TNFα antibody "(a) binds to an epitope on human [TNFα], [and] (b) inhibits binding of human [TNFα] to human [TNFα] cell surface receptors." The Court found that "[a] person of ordinary skill in the art would expect these mechanisms of action by the antibody as they had been known in the prior art by August 1, 1995." *Id.* at ¶ 361. Here, the '120 Patent adds a recitation that the anti–TNFα antibody "inhibits binding of human [TNFα] to both p55 and p75 cell surface receptors."

Abbvie contends that this mechanism is "an inherent part of the antibody's binding mechanism," and thus does not raise any new issue here. (Opening Br. at 17.) Indeed, Kennedy's expert, Dr. Peter Lipsky, testified at trial that this particular mechanism was "within

[5] *See generally Webster's Third New International Dictionary* 1920 (2002) (defining "remission" as "a temporary abatement of the symptoms of a disease").

the scope of" the '442 Patent. (Maldonado Decl. Ex. 7 at 632.) Moreover, his deposition testimony from the Prior Action demonstrates his understanding that the '442 Patent's language concerning "cell surface receptors" refers to the p55 and p75 receptors. He explained that since "[t]here are only two" cell surface receptors, he "assume[d] that means p55 and p75." (*See* Shehigian Decl. Ex. 14 at 250– 251.) He stated that he drew that conclusion based on "the literature of that time" relevant to the '442 Patent (*id.* at 251), whose prior art is coextensive with that of the '120 Patent.

Kennedy does not directly dispute that this binding mechanism is inherent,[6] but rather asserts that it was "unknown as of 1993." (Opp'n at 18.) Yet the study Kennedy cites does not state that the mechanism was unknown, but rather that it "was not established in this study." (Maldonado Decl. Ex. 12 at 1688.) Therefore, Kennedy has not raised a genuine dispute of fact regarding whether the claimed mechanism was known.

Moreover, even if there were a genuine dispute about whether the mechanism was known, it would be immaterial because there is also no dispute that the mechanism is an inherent feature of the invention. Merely describing an inherent property or mechanism of the prior art, without more, does not render a claim patentably distinct. *See, e.g.*, *Alcon Research, Ltd. v. Apotex Inc.*, 687 F.3d 1362, 1369 (Fed. Cir. 2012) (claimed limitation was obvious where it was an "inherent property"), *cert. denied*, 133 S. Ct. 1736 (2013); *In re Huai-Hung Kao*, 639 F.3d 1057, 1070 (Fed. Cir. 2011) (concluding that even where the claimed limitation was a

[6] Kennedy disputes only that the Court considered the inherency issue in the Prior Action. (*See* Def.'s R. 56.1 Stmt. ¶ 78.) Here, Kennedy contends that "AbbVie has not cited any admissible evidence" on the issue. (*Id.*) On the contrary, Abbvie has cited the prior testimony of Kennedy's expert, which could be "presented in a form that would be admissible in evidence," Fed. R. Civ. P. 56(c)(2), namely his live testimony at trial. *See Donovan v. Diplomat Envelope Corp.*, 587 F. Supp. 1417, 1426 (E.D.N.Y. 1984) ("All that is required is that the affiant or deponent make statements which *would* be admissible in evidence if given as testimony."), *aff'd*, 760 F.2d 253 (2d Cir. 1985).

"previously-unknown, yet inherent" property, it "add[ed] nothing of patentable consequence"); *In re Kubin*, 561 F.3d 1351, 1357 (Fed. Cir. 2009) ("Even if no prior art of record explicitly discusses the [binding mechanism], the [applicant's] application itself instructs that [such] binding is not an additional requirement imposed by the claims on the [molecule], but rather a property necessarily present in [the molecule]."); *CollaGenex Pharm., Inc. v. IVAX Corp*, 375 F. Supp. 2d 120, 137 (E.D.N.Y. 2005) ("When a process described in a later patent is inherent, although not specifically described, in the claims of an earlier patent owned by the same person, the later patent is likely invalid under the judicially created doctrine of obviousness-type double patenting."). Accordingly, there is no new ODP issue raised by the '120 Patent's additional language concerning the mechanism of action.

D. Comparison of Claims "As a Whole" With Prior Art

Taking the differences between the '120 Patent and the '442 Patent in the context of their importance to the invention as a whole, it is clear that they raise no new issue bearing on the ODP analysis. Not only does the '120 Patent merely limit its claims to those that were already clearly covered by the prior two patents, it has done so in ways that the Court actually considered in the Prior Action. A patentee like Kennedy may seek to adjust its claims in response to actions by a patent examiner or by a court, but Kennedy has failed to do so here in any way that would materially affect the Court's prior ODP analysis. In essence, Kennedy has claimed the same treatment as a new invention—but with limitations to treat sicker patients, for a specific outcome, and by a specific mechanism that was inherent in the prior art. As with the narrowed claims of the '442 Patent, this is precisely the kind of insubstantial tinkering on a previous patent that the ODP doctrine renders unpatentable.

Accordingly, the Court determines that the interests of "justice and equity" weigh strongly against relitigating issues that are "substantially identical" to those adjudicated in the Prior Action. *See Bourns*, 537 F.2d at 491, 497–98 (applying collateral estoppel "despite verbal differences in the claims" because plaintiffs had already "had their one day in court on those issues").

CONCLUSION

For the foregoing reasons, the Court GRANTS Plaintiffs' motion for summary judgment. The Clerk of Court is directed to enter judgment declaring that claims 1–2, 6–8, 12–14, and 18–19 of U.S. Patent No. 8,383,120 are invalid and to close this case.

Dated: New York, New York
July 9, 2014

SO ORDERED

PAUL A. CROTTY
United States District Judge